

Remarks/Arguments:

The specification is amended, hereby, to include domestic and PCT priority claims, in order to advance prosecution. The Office Action maintains that the priority claims are not found in the specification, but the Office Action is incorrect. The specification was, in fact, amended to include the priority claims in the transmittal papers filed with the subject continuation application.

A new Abstract is provided, hereby, as required in the Office Action.

The specification is objected to for allegedly lacking antecedent basis for the "optically active derivative" of the compound of formula (4), recited in the claims. The statement of objection is incorrect. Antecedent basis is found in the specification at page 24, lines 14-15, and the text including the last paragraph on page 19 and the reaction scheme appearing at the top of page 20. Withdrawal of the objection appears to be in order.

Claims 26-31, presented hereby, are pending.

Claims 25 is canceled, hereby, without prejudice or disclaimer.

New claim 26 corresponds to claim 25 amended by limiting the "protecting group for alcohol" to a group selected from "a silyl ether-protecting group, a phenyl-substituted methyl-protecting group, and an acetal-protecting group."

New claim 27 limits the compound of claim 26 to "the silyl ether-protecting group [that] is triethylsilyl, tert-butyldimethylsilyl or tert-butyldiphenylsilyl, the phenyl-substituted methyl-protecting group [that] is benzyl, p-methoxybenzyl or trityl, and the acetal-protecting group [that] is tetrahydropyranyl or methoxyl."

New claim 28 limits claim 26 to the compound "wherein R² is a phenyl-substituted methyl-protecting group and R¹ is trityl." New claim 29 limits the compound of claim 28 to "wherein R² is benzyl."

New claim 30 limits claim 26 to the compound "wherein R² is tert-butylmethylsilyl, and R¹ is a phenyl-substituted methyl-protecting. New claim 31 limits the compound of claim 30 to "wherein R¹ is trityl."

Support for the new claims can be found in examples of R¹ and R² disclosed at pages 11-12 of the present specification. New claims 28-31 are also supported by specification Examples 1 and 2.

Claim 25 was rejected under 35 USC 101 and 35 USC 112, ¶1, for allegedly lacking a practical utility and enablement for a practical use. Reconsideration is requested.

According to the statements of rejection, the presently claimed compound fails to satisfy the requirements of the statute for a practical utility based on the holding in *Bindra v. Kelly*, 206 USPQ 570, 575 (Bd. Pat. Inter. 1979). *Bindra*, according to the rejection, ruled that an "intermediate useful to make another intermediate" lacks practical utility. Reliance on *Bindra* is misplaced.

Bindra had nothing to do with whether utility as an intermediate is a practical utility under the statute. In fact, *Bindra* had nothing to do with what constitutes a practical utility. The issue in *Bindra* was not whether the claimed compound actually had a practical utility; the issue was whether the inventor could prove actual reduction to practice by a critical date, which proofs must include test results on use (i.e., utility) of the claimed compound that are unequivocally successful. In

Bindra the tests results were not unequivocally successful, only showing that success was *probable*.

See MPEP 2138.05, i.e.:

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." *Bindra v. Kelly*, 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.

In contrast to the facts presented in *Bindra*, there is no actual reduction to practice at issue in the present case; *constructive* reduction to practice was established by filing the subject patent application.

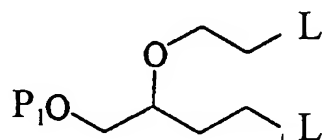
In point of fact, moreover, the compound (4) is not disclosed as an "intermediate useful to make another intermediate," as alleged. Compound (4) is the immediate precursor of compound (1), which has a known practical utility as an antidiabetic.

The requirements for showing practical utility are satisfied for the presently claimed compound, in that it is useful in making a compound – the compound (1) described in the subject application – having a known, practical utility. See *In re Breslow*, 205 USPQ 221, 226 (CCPA 1980) (even unstable, transitory chemical intermediates are patentable). Accordingly, withdrawal of the rejections under §101 and §112, ¶1, appears to be in order.

Claim 25 is rejected under 35 USC 102(a) as being allegedly anticipated by Engel (US 5,710,145). Reconsideration is requested.

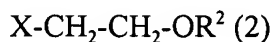
According to the statement of rejection (Office Action, page 5) (emphasis added), "Engel discloses a compound having the claimed formula (4) (see compound (III) and column 5, lines 52-57, wherein P₁ is a hydroxy protecting group and L is preferably O-mesyl). Mesyl is a well-known hydroxy protecting group."

In Engel (columns 5-6) the following compound (III) is disclosed:



However, Engel teaches that L is a good leaving group, such as chloro, bromo, iodo or mesyl* (CH₃SO₂-), or tosyl*, preferably) O-mesyl or Br (Engel column 5, lines 55-57) (mesyl* and tosyl* are mesyloxy and tosyloxy, respectively). According to the reference L means a leaving group, because compound (III) is intended to be reacted at L of said compound with the other reactive compound in the next step.

This compound (III) is just similar to the compound of the formula (2) disclosed in the subject application. At page 13, lines 3 to 6, of the present specification, the following compound of formula (2) is exemplified, for reacting with compound (3), to make the compound (4):



wherein X is a leaving group such as a halogen, e.g., chlorine or bromine, and a sulfonic acid ester, e.g., methanesulfonyloxy (mesyloxy) or p-toluensulfonyloxy (p-tosyloxy) and R² is a protecting group for hydroxy.

Comparison of compound (III), above, with compound (2), shows that "L" in compound (III) of Engel, and "X" in compound (2) have the same function.

Applicants do not deny that the mesyl(oxy) group and the tosyl(oxy) group are used as a hydroxy protecting group. However, it is readily apparent that a chemical group can not, usually, function as both a leaving – i.e., reactive – group and a protecting – i.e., non-reactive – group. In the special case when the reaction proceeds without affecting a leaving group, then, of course, the leaving group can function as a protecting group.

In any event, as mentioned above, the groups which have both functions (protecting and leaving) are clearly excluded from R^2 and R^1 in new claims.

Engel discloses protecting groups (P_1), such as TBDPS, etc. (Engel column 5, lines 52-55); but, the position occupied by P_1 – on compound (III) – is different than the position occupied by R^2 – on compound (4). Accordingly, Engel's disclosure of compound (III) fails to meet the particular features of the compound of present claims 26-31.

Accordingly, all features (limitations) of the presently claimed compound, as arranged in the claims, not being found in Engel, anticipation based on Engel is negated. For anticipation under §102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The absence from a prior art reference of a single claim limitation negates anticipation. *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim,

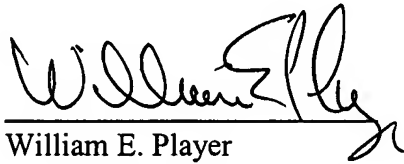
each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). Withdrawal of the rejection under §102(a) appears to be in order.

Favorable action is requested.

Respectfully submitted,

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